REMARKS

The Office Action mailed July 25, 2003 (Paper No. 15) has been carefully reviewed and the following is made in response thereto. Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

The amendments to the specification are made solely to update the status of U.S. application 08/320,982, which is now U.S. Patent No. 5,801,026.

Applicants respectfully submit that no prohibited new matter has been introduced by the amendments. Support for the amendments to the claims can be found throughout the specification and claims as originally filed. Entry of the amendment is respectfully requested.

Status of the Claims

Claims 22, 23, 27, 31-36 have been newly canceled without prejudice or disclaimer. Claims 37-41 are newly added. Thus, as a result of this amendment, newly added claims 37-41 are now pending.

Indication that the Claims are Free of the Prior Art

Applicants acknowledge, with appreciation, the indication made on page 8 of the Office Action that the claims are free of the prior art.

Information Disclosure Statements

Applicants acknowledge, with appreciation, return of signed, initialed and dated PTO Form 1449 filed on June 21, 2001.

Objection to the Specification

The specification has been amended to update the status of U.S. application 08/320,982, now U.S. Patent No. 5,801,026 as requested in the Office Action at paragraph no. 2, page 2. Withdrawal of the objection is requested.

Drawings

The Examiner has objected to the drawings allegedly "because Figure 10 has only been provided with handwritten figure legends" and stated that failure to file a corrected drawing will result in abandonment of the application.

Applicants do not understand this objection as a complete set of formal drawings was filed on October 31, 2001. A copy of the date stamped receipt from the U.S. PTO is attached for the Examiner's reference, along with a copy of the Response to Notice To File Corrected Applications Papers and another copy of the as-filed formal drawing for Figure 10. The date stamped receipt indicates that Figures 1A-11 were filed on October 31, 2001 and the Response states that "attached hereto are substitute drawings with appropriate margins". Our copy of the complete as-filed Response includes copies of all of the formal drawings for Figures 1A-11, including one for Figure 10.

Applicants request that the Examiner withdraw the objection or inform them if they need to incur the expense of having a graphic artist prepare a duplicate formal figure for Figure 10.

The Rejection of Claims under 35 U.S.C. § 112, Second Paragraph

Claims 22, 23, 27 and 31-36 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse the rejection as it applies to newly presented claims 37-41.

Claims 22 and 23, and claims dependent thereon, are alleged to be indefinite in their recitation of "seeds of the same plant" since "the seeds having increased hydroxylated fatty acid content could not be from the same plant, but could be from a plant of the same species" Claims 22 and 23 have been newly canceled without prejudice or disclaimer. Without acquiescing to the grounds of the rejection and solely in an effort to expedite prosecution, Applicants' newly presented claims require that the modified and unmodified plants referenced in the claims be from the same plant species. Withdrawal of the rejection is requested.

Claim 32 is alleged to be indefinite because it is asserted that it is allegedly not clear what is intended by the term "Canola." The Office Action suggests that Applicants "amend the claims to recite "*Brassica napus*", instead of "Canola" and that "rapeseed" also be deleted from the

claim". Without acquiescing to the grounds of the rejection and solely in an effort to expedite prosecution, Applicants have submitted new dependent claims 39 and 40 that do not recite "Canola" or "rapeseed" and newly recite "*Brassica napus*" in place thereof. One of ordinary skill in the art recognizes that "*Brassica napus*" is the scientific name for the group of plants commonly referred to as canola, rape and/or oilseed rape. See, *e.g.*, III. Crop Nomenclature: Scientific Names, In Glossary of Crop Science Terms, Robert F. Barnes and James B. Beard (eds.), page 73, Crop Science Society of America, July 1992 (copy attached for reference). Withdrawal of the rejection is requested.

Claim 35 is alleged to be indefinite because it does not further limit the claims from which it depends. Without acquiescing to the grounds of the rejection and solely in an effort to expedite prosecution, Applicants have newly canceled claim 35. Withdrawal of the rejection is requested.

The Rejection of Claims under 35 U.S.C. § 112, First Paragraph

Claims 22, 23, 27, 31-33 and 35-36 stand rejected under 35 U.S.C. § 112, first paragraph because they are alleged to lack written description support. Applicants respectfully traverse the rejection as far as it relates to newly pending claims 37-41.

The Office Action acknowledges that the specification describes transformed *Arabidopsis* plants having elevated levels of hydroxylated fatty acids compared to non-transformed plants but asserts that 1) there is allegedly no description provided regarding the level of hydroxylated fatty acid content in the non-transformed plant to which the comparison is made; 2) the specification allegedly does not set forth what the level of each and every hydroxylated fatty acid would be from plant species that have not been transformed; 3) it is allegedly impossible to determine what the characteristics are of oil having an increased content of fatty acids; 4) the specification allegedly does not provide written description that would allow a person skilled in the art to distinguish oil that is claimed from oil that comprises at least one hydroxylated fatty acid; and 5) it is alleged that no transformed plants other than *Arabidopsis* have been described.

Applicants respectfully disagree with the basis of the rejection for the following reasons.

As a first point, Applicants point out that there is no requirement in U.S. patent law that every claimed embodiment to be present in the application as an Example. All that is required is

that the application contain a "written description of the invention." 35 U.S.C. § 112, first paragraph. Applicants respectfully assert that the present claims fully meet this requirement because the characteristics of the claimed oil are described in sufficient detail such that a person having ordinary skill in the art would recognize that Applicants were in possession of the claimed invention at the time of filing.

The Office Action asserts in point 1) recited above, that there is allegedly no description provided regarding the level of hydroxylated fatty acid content in the non-transformed plant to which the comparison is made. Applicants respectfully disagree. All that is required is that the claimed triglyceride oil have an increased hydroxylated fatty acid content compared to triglyceride oil obtained from seeds of the same plant species without the recombinant DNA construct. It is irrelevant what the level is of the hydroxylated fatty acid content in the non-transformed plant because all that is required is that the claimed oil have an increased level. Determining if one triglyceride oil has an increased level compared to another triglyceride oil is a simple matter of making a direct comparison of the hydroxylated fatty acid content in each sample. Furthermore, Applicants have provided gas chromatography and mass spectrometry data for lipids extracted from Arabidopsis seeds of the wild type and from Arabidopsis seeds of transgenic lines containing the introduced nucleic acid coding for kappa hydroxylase. For example, a discussion of the obtained chromatographic and spectrometry results are provided at pages 40-46, including Table 1; and in Figures 3A-3B and 4A-4D. The comparison data clearly demonstrates a higher level of triglyceride hydroxylated fatty acid in the lipids of the transformed plants versus the wild type plants.

The Office Action asserts in point 2 above, that the specification allegedly does not set forth what the level of each and every hydroxylated fatty acid would be from plant species that have not been transformed. Applicants respectfully disagree. Again, it is irrelevant what the level of each and every hydroxylated fatty acid would be from plant species that have not been transformed because all that is required is that the claimed triglyceride oil have an increased level. Determining if one triglyceride oil has an increased level compared to another triglyceride oil is a simple matter of making a direct comparison of the hydroxylated fatty acid content in each sample. It is an easy matter to look at results such as those from gas chromatography and mass spectrometry as taught in the specification so as to see whether the hydroxylated fatty acid

content has been increased in accordance with the methods of this invention. As demonstrated in the Examples of the specification, transforming a plant with a nucleic acid encoding a kappa hydroxylase will result in the production of plants with increased levels of hydroxylated fatty acid content in the seed lipids obtained from the transformed plants as compared to the non-transformed plants of the same species.

The Office Action asserts in point 3 above, that it is allegedly impossible to determine what the characteristics are of triglyceride oil having an increased content of fatty acids. Applicants respectfully disagree. The characteristic recited in the claims which is relevant to whether or not the triglyceride oils have been sufficiently described is that the triglyceride oil have an increased level of hydroxylated fatty acid content compared to triglyceride oil obtained from seeds of the same plant species without the recombinant DNA construct. Other characteristics that the triglyceride oils may or may not have are simply not relevant.

The Office Action asserts in point 4 above, that the specification allegedly does not provide written description that would allow a person skilled in the art to distinguish the triglyceride oil that is claimed from triglyceride oil that comprises at least one hydroxylated fatty acid. Applicants respectfully disagree. All that is required is that the claimed triglyceride oil have an increased hydroxylated fatty acid content compared to triglyceride oil obtained from seeds of the same plant species without the recombinant DNA construct. Determining if one triglyceride oil has an increased level compared to another triglyceride oil is a simple matter of making a direct comparison of the hydroxylated fatty acid content in each sample using the methodology set forth in the specification.

The Office Action asserts in point 5 above, that no transformed plants other than *Arabidopsis* have been described. Applicants respectfully disagree. Applicants exemplify transformed *Arabidopsis* plants in the Examples. Applicants also state on pages 45-46 that *Arabidopsis* is widely accepted by plant biologists as a model for higher plants and the exemplification in the application of transformed *Arabidopsis* is meant to demonstrate the general utility of the invention in higher plants. Included within these higher plants are closely related species such as the crop plants *Brassica napus, Brassica juncea* or *Crambe abyssinicaa*. As stated previously, there is no requirement in U.S. patent law for every embodiment of a

claimed invention to be exemplified in a patent application. All that is required is that the application contain a "written description of the invention." 35 U.S.C. § 112, first paragraph.

The Examiner is respectfully requested to withdraw the written description rejection in view of the newly presented claims and for the reasons stated above.

Claims 22, 23, 27, 31-33 and 35-36 stand rejected under 35 U.S.C. § 112, first paragraph because while being enabled for triglyceride oil obtained from Arabidopsis that has been transformed with a nucleic acid sequence encoding a fatty acid hydroxylase, which comprises ricinoleic, lesquerolic, densipolic, and auricolic acid, allegedly does not provide enablement for triglyceride oil from a plant that has been transformed with a nucleic acid sequence that encodes a fatty acid hydroxylase, wherein said triglyceride oil has a hydroxylated fatty acid content that is increased compared to the hydroxylated fatty acid content from a triglyceride oil obtained from seeds of the same plant that has not been transformed with a nucleic acid sequence that encodes a fatty acid hydroxylase. Applicants respectfully traverse the rejection as far as it relates to newly pending claims 37-41.

Each of newly presented claims 37-41 require that the triglyceride oil with the increased hydroxy fatty acid and/or ricinoleic acid content be obtained from a plant "which has been modified to include a nucleic acid sequence coding for a kappa hydroxylase". Applicants refer the Examiner to the discussion immediately above as support that the full scope of the pending claims is fully supported by the as-filed specification.

Applicants have demonstrated that they were able to obtain triglyceride oil characterized by its hydroxy fatty acid content by transforming a model plant species (*i.e.*, Arabidopsis) with a nucleic acid encoding a kappa hydroxylase. The plant species utilized by Applicants is universally recognized as a model system used to study plant genetics, wherein the results of such studies have wide-spread application to many, if not most, plant species in the world. For example, The Agbiotech Inforsource (Issue 40, (November 1998) copy attached) states the following:

> "The *Arabidopsis* genes that guide the production of oils are closely related to those that produce oils in crops like soybeans and canola. The understanding of these genes has been used to identify corresponding genes in oilseed crops."

As another example, Focks and Benning (Plant Physiol. 118:91-101 (1998), copy attached), in discussing their genetic research on oil deposition in developing seeds, state the following:

> "Although canola seems to be more suitable for the physiological approach described above, its close relative Arabidopsis is the better genetic model organism."

One of ordinary skill in the art recognizes that transforming other seed-bearing plant species as taught by Applicants' invention using Arabidopsis as a model will result in the production of triglyceride oil with an altered hydroxy fatty acid content. For these reasons, the Examiner is respectfully requested to withdraw the rejection.

Conclusion

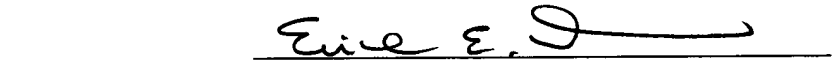
In view of the foregoing remarks, Applicants respectfully request withdrawal of all outstanding rejections and early notice of allowance to that effect. Should the Examiner believe that a telephonic interview would expedite prosecution and allowance of this application, she is encouraged to contact the undersigned at her convenience.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No.50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

Date: January 26, 2004



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